Maurice R. Hilleman (NAS) is Director (formerly Senior Vice President) of the Merck Institute at Merck Research Laboratories in West Point, Pennsylvania. His career has been in basic and applied research on viruses, vaccines, immunology, and cancer. He is a long-time adviser to many health agencies including the Department of Health and Human Services, WHO, Overseas Medical Research Laboratory Committee of the Department of Defense (DOD), and special committees of the NAS and IOM.

Peter B. Jahrling is Scientific Adviser and Senior Research Scientist at the United States Army Medical Research Institute of Infectious Diseases (USAMRIID). He is head of the WHO collaborating center on arbovirus and hemorrhagic fever virus research at USAMRIID and a member of the Committee on Return of Biological Samples of the National Research Council's (NRC's) Space Studies Board. He serves as a guest editor for a number of journals including the third and fourth editions of the *Biosafety in Microbiological and Biomedical Laboratories*. His research interests include development of vaccines, antiviral drugs, and effective treatment strategies for Ebola, Marburg, Lassa, and orthopox viruses.

James Leduc is Associate Director for Global Health in the National Center for Infectious Diseases at CDC. He is a fellow of the American College of Epidemiology and has received numerous awards for outstanding work in epidemiology. He has served as a Medical Officer of WHO and as an Officer at the United States Army Medical Research and Development Command. His research interests include epidemiology of virus diseases, especially viral hemorrhagic fevers and new, emerging and reemerging diseases.

Matthew Meselson (NAS, IOM) is Thomas Dudley Cabot Professor of Natural Sciences at Harvard University and codirector of the Harvard-Sussex program on chemical and biological warfare armament and arms limitation. He has conducted research mainly in the field of molecular genetics and is recipient of the NAS Award in Molecular Biology, the Eli Lilly Award in Microbiology, and the Thomas Hunt Morgan Medal of the Genetics Society of America. He is a member of the Royal Society and the Academie des Sciences and has served as a consultant on chemical and biological weapons matters to U.S. government agencies.

Thomas Monath is Vice President of Research and Development at OraVax and Adjunct Professor at the Harvard School of Public Health. He has been engaged in programs of WHO and the National Vaccines Advisory Committee. He was formerly director of the Division of Vector-Borne Infectious Diseases, CDC, and Chief of Virology, USAMRIID. His research has included work on arboviruses, viral hemorrhagic fevers, bubonic plague, and other zoonotic diseases. He has served on various committees dealing with biological weapons (BW) issues.

Frederick A. Murphy is Professor at the School of Veterinary Medicine at the University of California-Davis. Formerly, he was dean of the school and earlier he was the director of the National Center for Infectious Diseases at CDC. He is recipient of the Presidential Rank Award and is a member of the German Academy of Natural Sciences. He has been a leader in viral pathogenesis, viral characterization, and taxonomy; his interests include public health policy, vaccine development, and new, emerging and reemerging diseases.

Major General Philip K. Russell (retired U.S. Army) is Professor of International Health at the School of Hygiene and Public Health, Johns Hopkins University. He received the Distinguished Service Medal before retiring from military service. He has served on numerous scientific committees including advisory committees to the CDC and WHO. He was also involved in the establishment of medical research facilities at military bases around the world.

Alexis Shelokov is Director of Medical Affairs with the Biologicals Development Center of the Salk Institute. He served as a member of the Expert Working Group on Biological and Toxin Weapons Verification of the Federation of American Scientists. He has been involved in the activities of WHO, NIH, and the U.S.-Japan Cooperative Medical Program. In addition, he served as the chairman of U.S. delegations on hemorrhagic fevers to the Soviet Union in 1965 and 1969.

STAFF MEMBERS

Christopher P. Howson is Director of the Board on International Health of the IOM. In his 11 years at NAS, he has directed 15 projects and in 1993 served as acting director of the IOM Medical Follow-up Agency. Before coming to NAS, he was senior epidemiologist at the American Health Foundation in New York City. He holds a Ph.D. in epidemiology from the University of California at Los Angeles.

Jo L. Husbands is Director of the NAS Committee on International Security and Arms Control. Before assuming that position, she was director of the NRC's Project on Democratization and senior research associate for its Committee on International Conflict and Cooperation. She holds a Ph.D. in political science from the University of Minnesota.

Glenn E. Schweitzer is Director of the Office for Central Europe and Eurasia of the National Research Council. From 1963 to 1966, he served as the first science officer at the American Embassy in Moscow, and from 1992 to 1994 he was the first executive director of the International Science and Technology Center in Moscow. He has also served as director of the Office of Toxic Substances and director of the Environmental Monitoring Systems Laboratory-Las Vegas of the U.S. Environmental Protection Agency.

Chaarles G. Fogelgren is Research Assistant for the NAS Committee on International Security and Arms Control. He holds a B.A. in anthropology from The George Washington University. His interests include chemical and biological weapons disarmament, evolution, ethics, parasitology, and emerging and reemerging diseases.

B
Extract from Statement of Work of DOD/NAS Contract

SCOPE

The CTR program is working with the Russian Federation to expedite the dismantlement of weapons of mass destruction, to encourage nonproliferation, and to promote conversion of military capabilities to peaceful, civilian applications. These efforts will support the CTR program by developing a cooperative support and research program to assist in conversion of the FSU BW personnel and facilities by redirecting work to public health and other peaceful, civilian research programs. The program will be executed by the NAS. NAS, the National Academy of Engineering, IOM, and the National Research Council will collaborate on this project.

OBJECTIVES

The basic objective of this effort is to support the conversion of former Soviet BW research personnel to work on international public health issues. The specific objective is to engage Russian BW researchers in continuing collaborative projects with the West as part of the global effort for research, surveillance, and monitoring of new, emerging and reemerging diseases. Some existing diseases that might be subjects for cooperative work include hantavirus and broader classes of hemorrhagic fevers, tick-borne encephalitis, malaria, tuberculosis, and human immunodeficiency virus (HIV)/AIDS. The specific types of research involved could include work on (1) surveillance and monitoring methods, (2) studies of pathogenesis, (3) diagnostic tests, (4) treatments, and (5) new vaccines.

C
Consultations and Visits

CONSULTATIONS IN UNITED STATES

Discussions with government organizations

- National Security Council
- Department of Defense
    - Office of the Secretary of Defense
    - Cooperative Threat Reduction Program Office
    - Office for International Security Policy
    - Defense Special Weapons Agency
    - Special Operations in Low Intensity Conflict
- United States Army Medical Research Institute of Infectious Diseases
- Department of State
    - Office of the Coordinator for Assistance and Cooperation with the former Soviet Union
    - Bureau of Political and Military Affairs
- Arms Control and Disarmament Agency
- Department of Energy
    - Initiatives for Proliferation Prevention
    - Chemical/Biological Nonproliferation Program
- Department of Commerce
    - Materials Technical Advisory Committee

Other government organizations providing information

- National Institutes of Health
- United States Deparment of Agriculture
- National Science Foundation
- Centers for Disease Control and Prevention
- National Aeronautics and Space Administration

Discussions with nongovernment organizations

- Civilian Research and Development Foundation
- Chemical and Biological Arms Control Institute
- Stimson Center
- University of Maryland

Discussions with other organizations

- United Nations Centre for Disarmament Affairs
- European Commission: DG XII

CONSULTATIONS AND VISITS IN RUSSIA

Special activities

- Roundtable at Petrovo-Dalnyee organized by Biopreparat with officials from Biopreparat and the President's Committee for Conventional Problems of Chemical and Biological Weapons and scientists from a variety of Russian research institutes
- Meeting in Moscow organized by the NAS with representatives from Biopreparat and several institutes of the Biopreparat complex

- International symposium in the Kirov region organized by the International Science and Technology Center (ISTC) with representatives of more than a dozen research institutions

Meetings

- Biopreparat
- Ministry of Health with representatives of several institutes of the ministry
- Russian Academy of Medical Sciences with representatives of several institutes of the academy
- Ministry of Science and Technology
- Russian Academy of Sciences
- Member of Defense Council
- Staff member of Duma Armed Services Committee
- ISTC
- U.S. Embassy: Science Section and Office of Defense Attaché

Visits for scientific discussions

- State Research Center for Applied Microbiology, Obolensk
- "Vector" State Research Center for Virology and Biotechnology, Koltsovo

Familiarization visits

- Volgo-Vyatka Applied Biotechnology Center, Kirov
- Biochemical Plant, Kirov
- Sanitary-Epidemiology Center, Kirov

D

Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous, or Other Gases, and of Bacteriological Methods of Warfare

Signed at Geneva June 17, 1925
Entered into force February 8, 1928
Ratification advised by the U.S. Senate December 16, 1974
Ratified by U.S. President January 22, 1975
U.S. ratification deposited with the government of France April 10, 1975
Proclaimed by U.S. President April 29, 1975

The Undersigned Plenipotentiaries, in the name of their respective Governments:

Whereas the use in war of asphyxiating, poisonous or other gases, and of all analogous liquids, materials or devices, has been justly condemned by the general opinion of the civilized world; and

Whereas the prohibition of such use has been declared in Treaties to which the majority of Powers of the World are Parties; and

To the end that this prohibition shall be universally accepted as a part of International Law, binding alike the conscience and the practice of nations;

Declare:

That the High Contracting Parties, so far as they are not already Parties to Treaties prohibiting such use, accept this prohibition, agree to extend this prohibition to the use of bacteriological methods of warfare and agree to be bound as between themselves according to the terms of this declaration.

The High Contracting Parties will exert every effort to induce other States to accede to the present Protocol. Such accession will be notified to the Government of the French Republic, and by the latter to all signatory and acceding Powers, and will take effect on the date of the notification by the Government of the French Republic.

The present Protocol, of which the French and English texts are both authentic, shall be ratified as soon as possible. It shall bear today's date.

The ratifications of the present Protocol shall be addressed to the Government of the French Republic, which will at once notify the deposit of such ratification to each of the signatory and acceding Powers.

The instruments of ratification of and accession to the present Protocol will remain deposited in the archives of the Government of the French Republic.

The present Protocol will come into force for each signatory Power as from the date of deposit of its ratification, and, from that moment, each Power will be bound as regards other powers which have already deposited their ratifications.

IN WITNESS WHEREOF the Plenipotentiaries have signed the present Protocol.

DONE at Geneva in a single copy, this seventeenth day of June, One Thousand Nine Hundred and Twenty-Five.

Source: U.S. Arms Control and Disarmament Agency

E

Convention on the Prohibtion of the Development, Production, and Stockpiling of Bacteriological (Biological) and Toxin Weapons and on Their Destruction

Signed at Washington, London, and Moscow April 10,1972
Ratification advised by U.S. Senate December 16, 1974
Ratified by U.S. President January 22, 1975
U.S. ratification deposited at Washington, London, and Moscow March 26, 1975
Proclaimed by U.S. President March 26, 1975
Entered into force March 26, 1975

The States Parties to this Convention

Determined to act with a view to achieving effective progress towards general and complete disarmament, including the prohibition and elimination of all types of weapons of mass destruction, and convinced that the prohibition of the development, production and stockpiling of chemical and bacteriological (biological) weapons and their elimination, through effective measures, will facilitate the achievement of general and complete disarmament under strict and effective international control,

Recognizing the important significance of the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925, and conscious also of the contribution which the said Protocol has already made, and continues to make, to mitigating the horrors of war,

Reaffirming their adherence to the principles and objectives of that Protocol and calling upon all States to comply strictly with them,

Recalling that the General Assembly of the United Nations has repeatedly condemned all actions contrary to the principles and objectives of the Geneva Protocol of June 17, 1925,

Desiring to contribute to the strengthening of confidence between peoples and the general improvement of the international atmosphere,

Desiring also to contribute to the realization of the purposes and principles of the Charter of the United Nations,

Convinced of the importance and urgency of eliminating from the arsenals of States, through effective measures, such dangerous weapons of mass destruction as those using chemical or bacteriological (biological) agents,

Recognizing that an agreement on the prohibition of bacteriological (biological) and toxin weapons represents a first possible step towards the achievement of agreement on effective measures also for the prohibition of the development, production and stockpiling of chemical weapons, and determined to continue negotiations to that end,

Determined, for the sake of all mankind, to exclude completely the possibility of bacteriological (biological) agents and toxins being used as weapons,

Convinced that such use would be repugnant to the conscience of mankind and that no effort should be spared to minimize this risk,

Have agreed as follows:

Article I

Each State Party to this Convention undertakes never in any circumstances to develop, produce, stockpile or otherwise acquire or retain:

(1) Microbial or other biological agents, or toxins whatever their origin or method of production, of types and in quantities that have no justification for prophylactic, protective or other peaceful purposes;

(2) Weapons, equipment or means of delivery designed to use such agents or toxins for hostile purposes or in armed conflict.

Article II

Each State Party to this Convention undertakes to destroy, or to divert to peaceful purposes, as soon as possible but not later than nine months after the entry into force of the Convention, all agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, which are in its possession or under its jurisdiction or control. In implementing the provisions of this article all necessary safety precautions shall be observed to protect populations and the environment.

Article III

Each State Party to this Convention undertakes not to transfer to any recipient whatsoever, directly or indirectly, and not in any way to assist, encourage, or induce any State, group of States or international organizations to manufacture or otherwise acquire any of the agents, toxins, weapons, equipment or means of delivery specified in article I of the Convention.

Article IV

Each State Party to this Convention shall, in accordance with its constitutional processes, take any necessary measures to prohibit and prevent the development, production, stockpiling, acquisition, or retention of the agents, toxins, weapons, equipment and means of delivery specified in article I of the Convention, within the territory of such State, under its jurisdiction or under its control anywhere.

Article V

The States Parties to this Convention undertake to consult one another and to cooperate in solving any problems which may arise in relation to the objective of, or in the application of the provisions of, the Convention. Consultation and cooperation pursuant to this article may also be

undertaken through appropriate international procedures within the framework of the United Nations and in accordance with its Charter.

Article VI

(1) Any State Party to this Convention which finds that any other State Party is acting in breach of obligations deriving from the provisions of the Convention may lodge a complaint with the Security Council of the United Nations. Such a complaint should include all possible evidence confirming its validity, as well as a request for its consideration by the Security Council.

(2) Each State Party to this Convention undertakes to cooperate in carrying out any investigation which the Security Council may initiate, in accordance with the provisions of the Charter of the United Nations, on the basis of the complaint received by the Council. The Security Council shall inform the States Parties to the Convention of the results of the investigation.

Article VII

Each State Party to this Convention undertakes to provide or support assistance, in accordance with the United Nations Charter, to any Party to the Convention which so requests, if the Security Council decides that such Party has been exposed to danger as a result of violation of the Convention.

Article VIII

Nothing in this Convention shall be interpreted as in any way limiting or detracting from the obligations assumed by any State under the Protocol for the Prohibition of the Use in War of Asphyxiating, Poisonous or Other Gases, and of Bacteriological Methods of Warfare, signed at Geneva on June 17, 1925.

Article IX

Each State Party to this Convention affirms the recognized objective of effective prohibition of chemical weapons and, to this end, undertakes to continue negotiations in good faith with a view to reaching early agreement on effective measures for the prohibition of their development, production and stockpiling and for their destruction, and on appropriate measures concerning equipment and means of delivery specifically designed for the production or use of chemical agents for weapons purposes.

Article X

(1) The States Parties to this Convention undertake to facilitate, and have the right to participate in, the fullest possible exchange of equipment, materials and scientific and technological information for the use of bacteriological (biological) agents and toxins for peaceful purposes. Parties to the Convention in a position to do so shall also cooperate in contributing individually or together with other States or international organizations to the further development and application of scientific discoveries in the field of bacteriology (biology) for prevention of disease, or for other peaceful purposes.

(2) This Convention shall be implemented in a manner designed to avoid hampering the economic or technological development of States Parties to the Convention or international

cooperation in the field of peaceful bacteriological (biological) activities, including the international exchange of bacteriological (biological) agents and toxins and equipment for the processing, use or production of bacteriological (biological) agents and toxins for peaceful purposes in accordance with the provisions of the Convention.

Article XI

Any State Party may propose amendments to this Convention. Amendments shall enter into force for each State Party accepting the amendments upon their acceptance by a majority of the States Parties to the Convention and thereafter for each remaining State Party on the date of acceptance by it.

Article XII

Five years after the entry into force of this Convention, or earlier if it is requested by a majority of Parties to the Convention by submitting a proposal to this effect to the Depositary Governments, a conference of States Parties to the Convention shall be held at Geneva, Switzerland, to review the operation of the Convention, with a view to assuring that the purposes of the preamble and the provisions of the Convention, including the provisions concerning negotiations on chemical weapons, are being realized. Such review shall take into account any new scientific and technological developments relevant to the Convention.

Article XIII

(1) This Convention shall be of unlimited duration.

(2) Each State Party to this Convention shall in exercising its national sovereignty have the right to withdraw from the Convention if it decides that extraordinary events, related to the subject matter of the Convention, have jeopardized the supreme interests of its country. It shall give notice of such withdrawal to all other States Parties to the Convention and to the United Nations Security Council three months in advance. Such notice shall include a statement of the extraordinary events it regards as having jeopardized its supreme interests.

Article XIV

(1) This Convention shall be open to all States for signature. Any State which does not sign the Convention before its entry into force in accordance with paragraph (3) of this Article may accede to it at any time.

(2) This Convention shall be subject to ratification by signatory States. Instruments of ratification and instruments of accession shall be deposited with the Governments of the United States of America, the United Kingdom of Great Britain and Northern Ireland and the Union of Soviet Socialist Republics, which are hereby designated the Depositary Governments.

(3) This Convention shall enter into force after the deposit of instruments of ratification by twenty-two Governments, including the Governments designated as Depositary of the Convention.

(4) For States whose instruments of ratification or accession are deposited subsequent to the entry into force of this Convention, it shall enter into force on the date of the deposit of their instruments of ratification or accession.

(5) The Depositary Governments shall promptly inform all signatory and acceding States of the date of each signature, the date of deposit of each instrument of ratification or of accession and the date of the entry into force of this Convention, and of the receipt of other notices.

(6) This Convention shall be registered by the Depositary Governments pursuant to Article 102 of the Charter of the United Nations.

Article XV

This Convention, the English, Russian, French, Spanish and Chinese texts of which are equally authentic, shall be deposited in the archives of the Depositary Governments. Duly certified copies of the Convention shall be transmitted by the Depositary Governments to the Governments of the signatory and acceding states.

IN WITNESS WHEREOF the undersigned, duly authorized, have signed this Convention.

DONE in triplicate, at the cities of Washington, London and Moscow, this tenth day of April, one thousand nine hundred and seventy-two.

Source: U.S. Arms Control and Disarmament Agency

F

Australia Group

Chaired by Australia, the "Australia Group" (AG) is an informal forum of states whose goal is to discourage and impede chemical weapons (CW) proliferation by harmonizing national export controls on CW precursor chemicals, sharing information on target countries, and seeking other ways to curb the use of CW.

The Group was formed in 1984 as a result of CW use in the Iran-Iraq war. Members meet annually in Paris, where the 1925 Geneva Protocol is deposited. The Group's actions are viewed as complementary measures in support of the 1925 Geneva Protocol, the 1972 Biological and Toxins Weapons Convention and the 1993 Chemical Weapons Convention.

There are presently 30 members of the Group, including: EC-12, Australia, Argentina, Austria, Czech Republic, Hungary, Iceland, New Zealand, Japan, Canada, Norway, Finland, Sweden, Switzerland, Poland, Romania, the Slovak Republic, South Korea, and the United States. Requests by other states to join the Group are considered on a case-by-case basis.

The Group has no charter or constitution. It operates by consensus. On December 10, 1992, the AG issued its first joint background paper on the Group's activities.

The Group has established common export controls for chemical and biological weapons nonproliferation purposes. For CW, members of the AG control a list of 54 chemical precursors and a list of CW-related production equipment as well. For BW, members have established export controls on certain microorganisms, toxins, and equipment that could be used in a BW program.

In tandem with export controls, the AG has periodically used warning mechanisms to sensitize its public to CBW proliferation. The Group has issued an informal "warning list" of dual-use CW precursors and bulk chemicals, and on CW-related equipment. Members develop and share the warning lists with their chemical industries and ask industry to report on any suspicious transactions. The AG has also used an approach to warn industry, the scientific community, and other relevant groups of the risk of inadvertently aiding BW proliferation.

The Group's meetings focus on sharing information about national export controls, considering proposals for "harmonization"—the adoption of common controls by all members on chemical precursors, equipment, biological weapons related materials, and considering other measures to address CBW proliferation and use.

LIST OF DUAL-USE BIOLOGICAL EQUIPMENT FOR EXPORT CONTROL

1. Complete containment facilities at P3, P4 containment level

   Complete containment facilities that meet the criteria for P3 or P4 (BL3, BL4, L3, L4) containment as specified in the WHO Laboratory Biosafety manual (Geneva, 1983) are subject to export control.

2. Fermenters*

Fermenters capable of cultivation of pathogenic micro-organisms, or viruses or of toxin production, without the propagation of aerosols, and having all the following characteristics:

(a) Capacity equal to or greater than 100 litres.

*Sub-groups of fermenters include bioreactors, chemostats and continuous-flow systems.

3. Centrifugal Separators*

Centrifugal separators capable of the continuous separation of pathogenic microorganisms, without the propagation of aerosols, and having all the following characteristics:

(a) Flow rate greater than 100 litres per hour;
(b) Components of polished stainless steel or titanium;
(c) Double or multiple sealing joints within the steam containment area; and
(d) Capable of in-situ steam sterilization in a closed state.

*Centrifugal separators include decanters.

4. Cross-flow filtration equipment

Cross-flow filtration equipment capable of continuous separation of pathogenic microorganisms, viruses, toxins, and cell cultures without the propagation of aerosols, having all the following characteristics:

(a) Equal to or greater than 5 square metres;
(b) Capable of in situ sterilization.

5. Freeze-drying equipment

Steam sterilizable freeze-drying equipment with a condensor capacity greater than 50 kg of ice in 24 hours and less than 1000 kg of ice in 24 hours.

6. Equipment that incorporates or is contained in P3 or P4 (BL3, BL4, L3, L4) containment housing, as follows:

(a) Independently ventilated protective full or half suits; and
(b) Class III biological safety cabinets or isolators with similar performance standards.

7. Aerosol inhalation chambers

Chambers designed for aerosol challenge testing with microorganisms, viruses, or toxins and having a capacity of 1 cubic metre or greater.

The experts propose that the following items be included in awareness-raising guidelines to industry:

1. Equipment for the microencapsulation of live microorganisms and toxins in the range of 1-10 μm particle size, specifically:

(a) Interfacial polycondensors; and
(b) Phase separators.

2. Fermenters of less than 100 litre capacity with special emphasis on aggregate orders or designs for use in combined systems.

3. Conventional or turbulent air-flow clean-air rooms and self-contained fan-HEPA filter units that may be used for P3 or P4 (BL3, BL4, L3, L4) containment facilities.

LIST OF BIOLOGICAL AGENTS FOR EXPORT CONTROL CORE LIST [1]

Viruses

V1. Chikungunya virus
V2. Congo-Crimean haemorrhagic fever virus
V3. Dengue fever virus
V4. Eastern equine encephalitis virus
V5. Ebola virus
V6. Hantaan virus
V7. Junin virus
V8. Lassa fever virus
V9. Lymphocytic choriomeningitis virus
V10. Machupo virus
V11. Marburg virus
V12. Monkeypox virus
V13. Rift Valley fever virus
V14. Tick-borne encephalitis virus (Russian spring-summer encephalitis virus)
V15. Variola virus
V16. Venezuelan equine encephalitis virus
V17. Western equine encephalitis virus
V18. White pox
V19. Yellow fever virus
V20. Japanese encephalitis virus

Rickettsiae

R1. *Coxiella burnetii*
R2. *Bartonella quintana (Rochalimea quintana, Rickettsia quintana)*
R3. *Rickettsia prowasecki*
R4. *Rickettsia rickettsii*

Bacteria

B1. *Bacillus anthracis*
B2. *Brucella abortus*

B3. *Brucella melitensis*
B4. *Brucella suis*
B5. *Chlamydia psittaci*
B6. *Clostridium botulinum*
B7. *Francisella tularensis*
B8. *Burkholderia mallei (Pseudomonas mallei)*
B9. *Burkholderia pseudomallei (Pseudomonas pseudomallei)*
B10. *Salmonella typhi*
B11. *Shigella dysenteriae*
B12. *Vibrio cholerae*
B13. *Yersinia pestis*

Genetically modified microorganisms

G1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the core list.

G2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the core list or their subunits.

Toxins as follows and subunits thereof:[2]

T1. Botulinum toxins
T2. *Clostridium perfringens* toxins
T3. Conotoxin
T4. Ricin
T5. Saxitoxin
T6. Shiga toxin
T7. *Staphylococcus aureus* toxins
T8. Tetrodotoxin
T9. Verotoxin
T10. Microcystin (Cyanginosin)
T11. Aflatoxins

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1. Except where the agent is in the form of a vaccine.
2. Excluding immunotoxins.

WARNING LIST[1]

Viruses

WV1. Kyasanur Forest virus
WV2. Louping ill virus
WV3. Murray Valley encephalitis virus
WV4. Omsk haemorrhagic fever virus
WV5. Oropouche virus
WV6. Powassan virus
WV7. Rocio virus

WV8. St. Louis encephalitis virus

Bacteria

WB1. *Clostridium perfringens**
WB2. *Clostridium tetani**
WB3. Enterohaemorrhagic *Escherichia coli*, serotype 0157, and other verotoxin-producing serotypes
WB4. *Legionella pneumophila*
WB5. *Yersinia pseudotuberculosis*

Genetically modified microorganisms

WG1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the warning list.

WG2. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences coding for any of the toxins in the warning list or their subunits.

Toxins as follows and subunits thereof:[2]

WT1. Abrin
WT2. Cholera toxin
WT3. Tetanus toxin
WT4. Trichothecene mycotoxins
WT5. Modeccin
WT6. Volkensin
WT7. Viscum album lectin 1 (Viscumin)

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*The Australia Group recognizes that these organisms are ubiquitous, but, as they have been acquired in the past as part of biological weapons programs, they are worthy of special caution.

1. Except where the agent is in the form of a vaccine.

2. Excluding immunotoxins.

LIST OF ANIMAL PATHOGENS FOR EXPORT CONTROL[1]

Viruses

AV1. African swine fever virus
AV2. Avian influenza virus[2]
AV3. Bluetongue virus
AV4. Foot and mouth disease virus
AV5. Goatpox virus
AV6. Herpesvirus (Aujeszky's disease)
AV7. Hog cholera virus (synonym: swine fever virus)
AV8. Lyssa virus
AV9. Newcastle disease virus

AV10. Peste des petits ruminants virus
AV11. Porcine enterovirus type 9 (synonym: swine vesicular disease virus)
AV12. Rinderpest virus
AV13. Sheeppox virus
AV14. Teschen disease virus
AV15. Vesicular stomatitis virus

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1. Except where the agent is in the form of a vaccine.

2. This includes only those avian influenza viruses of high pathogenicity as defined in EC Directive 92/401EC: "Type A viruses with an IVPI (intravenous pathogenicity index) in 6 week old chickens of greater than 1.2, or Type A viruses HS or H7 subtype for which nucleotide sequencing has demonstrated multiple basic amino acids at the cleavage site of haemagglutinin."

Bacteria

AB3. *Mycoplasma mycoides*

Genetically-modified microorganisms

AG1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity and are derived from organisms in the list.

CONTROL LIST OF PLANT PATHOGENS FOR EXPORT CONTROL

CORE LIST

Bacteria

PB1. *Xanthomonas albilineans*
PB2. *Xanthomonas campestris* pv. citri

Fungi

PF1. *Colletotrichum coffeanum var. virulans (Colletotrichum kanawae)*
PF2. *Cochliobolus miyabeanus (Helminthosporium oryzae)*
PF3. *Microcyclus ulei (*synonym *Dothidella ulei)*
PF4. *Puccinia graminis (*synonym *Puccinia graminis* f. sp. *tritici)*
PF5. *Puccinia striiformis (*synonym *Pucciniaglumarum)*
PF6. *Pyricularia grisea/Pyricularia oryzae*

Genetically modified Microorganisms

PG1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the export control list.

ITEMS FOR INCLUSION IN AWARENESS-RAISING GUIDELINES

Bacteria

PWB1. *Xanthomonas campestris* pv. oryzae
PWB2. *Xylella fastidiosa*

Fungi

PWF1. *Deuterophoma tracheiphila* (synonym *Phoma tracheiphila*)
PWF2. *Monilia rorei* (synonym *Moniliophthora rorei*)

Viruses

PWV1. Banana bunchy top virus

Genetically modified microorganisms

PWG1. Genetically modified microorganisms or genetic elements that contain nucleic acid sequences associated with pathogenicity derived from the plant pathogens identified on the awareness-raising list.

Source: U.S. Arms Control and Disarmament Agency

G

Conclusions of Roundtable on Bilateral Cooperation to Address the Public Health Aspects of Dangerous Pathogens
(Petrovo-Dalnyee, April 28-29,1997)

1. The Russian participants expressed their appreciation to the National Academy of Sciences and its Institute of Medicine for proposing the Roundtable on a topic of great importance to Russia and the United States. The American participants expressed their appreciation to RAO Biopreparat for organizing the Roundtable and for ensuring excellent working conditions and living arrangements.
2. The presentations and discussions underscored the importance of the contributions of American and Russian scientists to improving prophylaxis, epidemiological monitoring, and therapy of infectious diseases.
3. Expanded bilateral cooperation between American and Russian specialists could combine important and unique national capabilities of the two countries and of the broader international community to improve understanding of the characteristics of dangerous pathogens and to reduce risks to public health and national security.
4. An important confidence-building step would be an expansion of bilateral cooperation at the laboratory level in an atmosphere of transparency, with exchanges of scientists having experience with dangerous pathogens, including specialists who are working on defense topics, as well as other specialists.
5. The participants welcomed the progress in developing the initial collaborative research projects to be supported by the National Academy of Sciences through the International Science and Technology Center and to be carried out by the State Research Center for Virology and Biotechnology "Vector" and the State Research Center for Applied Microbiology.
6. In looking to the future, the participants discussed different approaches to expand cooperation. There are important issues that must be resolved at the governmental level and scientists can assist in identifying such issues as collaboration expands.
7. The Russian participants will establish a small working group to continue to provide suggestions to the National Academy of Sciences during the next several months as to future collaborative activities which would be important in improving the prophylaxis, epidemiological monitoring, and therapy of diseases caused by dangerous pathogens. The National Academy of Sciences will communicate with RAO Biopreparat concerning the next steps in this regard.

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Head of Russian Delegation

John Steinbruner
Head of American Delegation

Petrovo-Dalnyee
April 29, 1997

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Report of the International Symposium on "Severe Infectious Diseases: Epidemiology, Express-Diagnostics, and Prevention" Nizhne-Ivkino, Kirov Oblast June 16-20, 1997

The participants from a number of countries emphasized the importance of the topics discussed during the symposium, which are set forth in the attached agenda.

The problem of emerging and reemerging infections should be considered a top priority at both the national and international levels. The consequences of unpredictable epidemics which could be caused by these infections are very serious.

The urgent nature of the problem is based on the evolving nature of the genome and biological (e.g., antigenic) characteristics of pathogens. Such changes are the result of dramatic alterations in social and environmental conditions at both local and global levels. The natural migration of animals, the increasing movement of people, and modifications in ecosystems due to anthropogenic activities also contribute to the global spread of numerous zoonoses and zooanthroponoses. It is necessary to anticipate and predict such situations and conduct monitoring at the national and international levels in order to prevent and reduce the scope of epidemic events.

In the case of emergency epidemic situations, it is necessary to ensure adequate and timely diagnostics, as well as reliable vaccines and antimicrobials, including antivirals, and other preparations for saving human and animal lives. In this regard, the following approaches should be directed to the diseases of greatest concern (see Table 1 for examples of diseases):

a) Identify organisms for which vaccines, antiviral preparations, and antibiotics should be developed and specify groups which require immunization.

b) Employ the tremendous power of modern molecular microbiology and immunology toward the conception and design of the most effective, innovative vaccines against the most dangerous pathogens.

c) Apply the new knowledge obtained from basic molecular microbiologic research toward rapid vaccine production technology and effective distribution for the global prevention and control of catastrophic disease episodes.

d) Develop highly sensitive and specific methods of rapid diagnostics.

These areas were discussed in the reports during the symposium.

The reported experiments and data reflected the substantial progress which has been achieved in diagnosing and preventing emerging and reemerging infections. At the same time, a wide range of problems was identified. In some cases, solutions to these problems were proposed.

In addition to reports on fundamental research highlighting the basic pathogenesis of highly dangerous infections, molecular and genetic characteristics of their causative agents, and mechanisms of immunogenesis, attention also focused on results obtained from applied research. Such studies are aimed at improving techniques and methods of rapid diagnostics of highly dangerous infections and indication and identification of relevant pathogens, as well as developing new research efforts in the design of immunological and biological preparations.

The participants recognized the special contributions to public health which defense scientists can make and urged them to direct their efforts to improved prophylaxis, detection, and treatment of highly dangerous pathogens.

The participants of the symposium enthusiastically supported the idea of exchanges of specialists from different countries. It would facilitate the sharing of research results and the search for areas of mutually beneficial scientific cooperation and would provide a basis for joint research.

Expanded educational programs are needed to improve understanding among both health practitioners and the general public about practical measures that can be taken to reduce the risks of infections from dangerous pathogens.

Modern information and communications technologies are providing unprecedented opportunities for direct communications among scientists throughout the world. Governments and private organizations should ensure that these technologies are made available to scientists working on dangerous pathogens.

A continuing high level of attention should be given to all aspects of safe handling of dangerous pathogens, including the safe disposal of contaminated wastes.

Thus, it is clear that scientists must support the battle against epidemics which result in tremendous disasters inflicted on the world's population and cause 16 million deaths every year.

The participants expressed their sincere gratitude to the U.S. National Academy of Sciences and the International Science and Technology Center, which cosponsored the symposium, to the Volga-Vyatka State Scientific Center of Applied Biotechnology, which organized the event, and to the governor of Kirov Region, Academician V.N. Sergeenkov, for his special interest in the symposium.

The participants had an opportunity to visit the Kirov Biochemical Plant, the Vyatka Chamber of Commerce and Industry, and the facilities of the Sanitary Epidemiological Service and the Committee on Ecology in Kirov. Also, the participants welcomed the proposal of the Volgo-Vyatka State Scientific Center for Applied Biotechnology to serve as a point of contact for future cooperation with the region in fields related to the topics discussed at the symposium.

June 20, 1997

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NOTE: This list does not include unregistered exhibitors at the conference.

I
Descriptions of Pilot Projects

Project 1: The study of prevalence, genotype distribution, and molecular variability of isolates of hepatitis C virus in the Asian part of Russia

Description: This project focuses on sequencing and identifying genotypic variants of hepatitis C virus (HCV) in the Asian Russian population to determine the extent of variability of the virus in the region.

Importance: HCV is a serious public health problem in Russia, the United States, and globally. Approximately 2 percent of blood donors in Russia are infected with HCV, resulting in a 20 to 40 percent prevalence of infection in recipients of multiple transfusions. Fifteen isolates of HCV have been partially sequenced to date. This has led to the discovery of several nontypical genotypes that appear to have evolved independently in the isolated populations of Siberia and the Far East. There is a need for additional data on the extent of variability of the virus in Asian Russia (and elsewhere) for three reasons: (1) to determine whether commercially available tests can detect all current genotypic variants of HCV, (2) to ascertain how well vaccines in development will protect against these variants, and (3) and to provide an additional means for estimating the prevalence of HCV infection in the general population. The findings of this project should usefully inform national HCV prevention and control programs.

Project 2: Monkeypox virus genome

Description: This project focuses on sequencing the monkeypox virus genome.

Importance: Monkeypox is a classic emerging infectious disease. Sequencing the monkeypox virus genome will facilitate development of species-specific diagnostics based on polymerase chain reaction. In addition, comparison of the monkeypox virus genome with that of variola (smallpox) may reveal substantial duplication of gene functions, thereby contributing essential information relevant to the planned worldwide destruction of variola in 1999. Better understanding of the relation of structure to function in the monkeypox virus genome is also expected to provide insight into the rational design of effective antiviral drugs and therapeutic strategies for monkeypox and other orthopox viruses.

Project 3: Study of the genetic and serologic diversity of Hantavirus in the Asian part of Russia

Description: This project is cataloguing the genetic and serologic variability of hantaviruses collected from the Asian part of Russia.

Importance: Hemorrhagic fever with renal syndrome is a significant cause of human morbidity and mortality in the Asian part of Russia, with the disease extending to South Korea and China. Strains of classic Hantaan virus, found in China and Korea, are known to occur in far eastern Russia, whereas Puumala virus, predominant in European Russia, extends into Siberia and the Far East. In addition, other newly recognized Hantaviruses such as Khabarovsk virus exist in eastern Russia, but their potential to cause human illness has yet to be determined. Hantaviruses are emerging throughout the world, and it is currently unknown where new Asian strains fit in the phylogenetic tree. This study should yield important information about the serologic and genetic variability of Hantaviruses and help identify rodent hosts and risk factors for this important group of viral pathogens. These findings, in turn, could help inform research and development in support of effective vaccines against Hantavirus infection in the United States and Russia.

Project 4: Development of advanced diagnostic kit for opisthorchiasis in human patients

Description: This project is developing an advanced diagnostic kit for human opisthorchiasis.

Importance: The parasitic liver fluke *Opisthorchis felineus* represents a significant human health problem in much of Russia, with an estimated 10 to 20 million human infections in Siberia alone. Liver flukes in the same family are also found in contaminated fish in the northwestern

United States. Current diagnostic procedures rely on direct stool examination, which is time-consuming, technically difficult, and expensive. An enzyme immunoassay has been developed for serologic diagnosis but is limited in value because it is not able to differentiate between current infections and cured individuals. An effective treatment with phenolics is available, but these drugs are too toxic to use except to treat active infection; thus, there is an urgent need for an improved diagnostic test to differentiate active cases rapidly, accurately, and with minimum cost. Sufficient human samples are readily available to ensure that substantive evaluation of candidate assays will be conducted promptly, with preliminary results likely to be available during 1997.

Project 5: Molecular biological and immunochemical analysis of clinical strains of tuberculosis and mycobacteriosis

Description: This project focuses on characterization of different strains of mycobacteria in Russian patients diagnosed with tuberculosis (TB).

Importance: TB, particularly drug-resistant TB, represents a serious threat to the United States and is increasing in Russia in epidemic proportions. This project is characterizing different strains of mycobacteria isolated from Russian patients diagnosed with TB and is determining the spectrum of drug resistance among them. The relation between strain virulence and the spectrum and degree of drug resistance will be explored by identifying the genes responsible for drug resistance. New antibiotics under development in Russia will be tested for their potency against these clinical strains. This project will help strengthen Russian capability in addressing the emerging TB epidemic in Russia.

Project 6: Investigation of the immunological effectivity of delivery in vivo of the *Brucella* main outer membrane protein by anthrax toxin components

Description: This project is an initial step toward the eventual goal of producing an effective recombinant protein vaccine or vaccine mixture for veterinary use against *Brucella abortus* and for protection of occupationally exposed personnel.

Importance: Human brucellosis is a disease caused by species of the bacterium *Brucella*. In humans it is seriously debilitating but seldom lethal. Its principal reservoirs are cattle, sheep, and swine. Human exposure is principally from direct contact with infected animals and animal products, including consumption of unpasteurized milk and milk products from infected animals. Control of the disease in humans occurs mainly by avoiding the consumption of unpasteurized milk or milk products and contact with infected animals, sacrificing infected animals and herds, and, in areas where brucellosis is endemic, veterinary vaccination. None of the current vaccines against brucellosis is completely satisfactory; their shortcomings include incomplete protection, induction of abortion, and occasional infectivity to humans. This protocol calls for the construction of chimeric genes expressing anthrax lethal factor (LF)-*Brucella* outer membrane protein (OMP) fusion proteins and testing of the resulting chimeric proteins when administered together with anthrax protective factor for immunological effectiveness against *Brucella abortus*. The LF-protective antigen (PA) cell delivery system holds great promise for an improved brucellosis vaccine, in particular, and for more effective disease prevention in the United States and Russia generally.